DuPont Pharmaceuticals Company

9141 '00 MAY 31 A9:28

May 30, 2000

VIA FEDERAL EXPRESS

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: INTERNATIONAL CONFERENCE ON HARMONISATION; E11 CLINICAL INVESTIGATION OF MEDICINAL PRODUCTS IN THE PEDIATRIC POPULATION REQUEST FOR COMMENTS (DOCKET NO. 00D-1223)

Dear Sir or Madam,

Reference is made to the above-referenced draft guidance. Notice of availability of this draft guidance, as well as request for comment, was published in the April 12, 2000, edition of the FEDERAL REGISTER.

In response to this request for comments, attached is feedback from the DuPont Pharmaceuticals Co. on the content of the draft guidance.

We appreciate the opportunity to comment on this draft guidance.

Sincerely,

Jamie Warner

Jamie Warner
Associate Director
Regulatory Affairs

Submitted in Duplicate

00D-1223

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DOCKET NO. 00D-1223

INTERNATIONAL CONFERENCE ON HARMONISATION; E11 CLNICAL INVESTIGATION OF MEDIINAL PRODUCTS IN THE PEDIATRIC POPULATION

COMMENTS ON DRAFT GUIDANCE

SECTION 2.3
TIMING OF STUDIES

Section 2.3 discusses the timing of studies. While it is understandable to start pediatric trials early in Section 2.3.1 (Diseases Predominantly/Exclusively Affecting Pediatric Patients) and Section 2.3.2 (Serious/Life-Threatening Diseases--once reasonable evidence of potential benefit exists), we do not fully agree with the proposal in Section 2.3.3 (Medicinal Products Intended to Treat Other Diseases and Conditions). It states that testing in these populations would not usually begin until Phase 2 or 3. There is minimal discussion around risk benefit considerations. We believe that if the product does not address a clear medical need as in Sections 2.3.1 and 2.3.2, there should be a risk benefit analysis, addressing the incidence of the disease in pediatrics, the outcome of the disease, the alternatives available to treat the disease and the risks of exposing pediatrics to a novel product without a clearly-defined safety and efficacy profile in any population. The difficulty in recruiting patients into this type of study needs to be considered. The last line of this paragraph mentions risk-benefit; however, we believe that the risk-benefit is the most important consideration in starting studies in pediatric patients where there is not a clear unmet medical need.

SECTION 2.4.3
SAFETY

This section discusses safety and gaining a better understanding of the long-term effects of drugs in the pediatric population. While we agree that this is needed especially in drugs intended to treat pediatric diseases, it would seem valuable for the guidance document to discuss some other approaches that could be used versus "long term studies" for the category of drugs discussed in Section 2.3.3 (Medicinal Products Intended to Treat Other Diseases and Conditions).

GENERAL COMMENT

We believe that this guidance document should be revised to include other ways in which to collect pediatric data outside the well-controlled trial, i.e., discuss expanded access programs to gain exposure to new medicines especially when these products are approved in adult populations.

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